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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,111	09/15/2000	Charles J. Davidson	S63.2H-12013-US01	3759

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/663,111	DAVIDSON ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-8,10-19,42-48,50-70,72 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-8,10-19,42-48,50-70,72 and 73* is/are rejected.

7)☒ Claim(s) *1 and 72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Objections

Claims 1 and 72 are objected to because of the following informalities:

With regard to claims 1 and 72, it is unclear how the side member can be "fixedly attached" to the catheter and also be capable of sliding with respect thereto. "Fixed" denotes stationary or immovable with respect to some other element. For this reason, the use of the term "fixedly" is considered confusing in the context of the present invention. The Examiner suggests deleting "fixedly" on line 7 of each of claims 1 and 72 in order to overcome this objection.

In claim 72, last two lines, "the stent" lacks clear antecedent basis because 2 stents are being claimed previously in the claim. In order to overcome this ambiguity, the Examiner suggests inserting --catheter-- between "a" and "stent" (on line 5), and on the last line, insert ---catheter--- before "stent" (both occurrences).

Appropriate correction is required.

Claim Rejections Based Upon Prior Art

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-8, 10-13, 15-19, 42-48, 50-56, 58-70 and 72-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colombo et al (US 6,520,988) in view of

Uthmann (US 4,385,631) or Cameron (US 5,059,170). Colombo discloses an endoprosthesis delivery system where the markers can be put on all the elements including both dilators and on the side port (19) of the stent; see column 12, line 52 to column 13, line 20. These markers or indicators are all juxtapositioned in one configuration prior to deployment and located near or at the side port. The side member of Colombo is fixedly attached to the main catheter at least by the stent. The branch stent deployment device as claimed is the balloon portion of the side branch; see Figures 1 to 6 and column 12, line 52 to column 13, line 31. The statement on column 13, lines 11-17 that "the present invention contemplates providing a similar "side port" marker along the other dilator or access devices . . ." meets the limitation requiring a radiopaque marker on the catheter. The Examiner interprets this statement as disclosing that all other elements of the assembly (1) can have radiopaque markers on them.

Alternatively, one could view the markers of Colombo as not being positively juxtapositioned with respect to each other. However, since the markers are to locate the relative position of the stent near the vessel and to detect some change in the configuration, it is the Examiner's position that the putting them adjacent to one another would have been considered clearly obvious to an ordinary artisan.

However, Colombo fails to disclose that first and second radiopaque markers can be present on the catheter and/or side member or that the side member is attached to the catheter at a point proximal to the stent.

However, since Colombo teaches that multiple elements can have radiopaque markers, the mere duplication of part is considered to be clearly obvious in view thereof; see MPEP 2144.04 VI B that is incorporated herein by reference.

In addition, Uthmann (see the abstract and figures) or Cameron (see the abstract and figures) teaches that it was known to attach a side member and catheter to each other in a proximal location. Therefore, it is the Examiner's position that it would have been obvious to couple or attach the main and branch catheters together in a proximal region of the device for the same reasons that the Uthmann or Cameron does the same or to better prevent bleeding at the entrance site.

With regard to claims 8, 52, 72, and 73, the terminology "branch stent deployment device" and the "side member" had been and has been interpreted separate elements but Colombo teaches that a separate deployment device can be used to deliver a stent; see column 15, lines 53-64 and column 16, lines 46-52.

With regard to claims 50 and 73, it is not clear disclosure that the markers of Colombo are adjacent each other in one configuration and separated in a second configuration. However, since they are separate markers on different elements, they could be considered separated even when they are adjacent each other. Furthermore, it would have been considered at least obvious to have the markers become more separate in view of Colombo alone because a noticeable change in the configuration was contemplated by Colombo; see column 13, lines 3-20.

Regarding claims 16, 17, 61, and 62, Colombo fails to disclose a balloon inflation lumen, channels, and ports. However, since Colombo discloses balloons that can be

inflated by an operator of the device, it would have been obvious to have a lumen with channels and ports to deliver the inflation fluid to the balloons.

Regarding claims 19 and 64, Colombo fails to disclose the length of the detachment of the elements designated as the catheter and side member. However, it would have been obvious to a person of ordinary skill in the art to have a 2 to 10 cm detachment length because Applicants have not disclosed that having such provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because it would be suitably sized for the particular bifurcation point.

With regard to claim 42-44 and 66-68, Colombo discloses attaching the main and side catheters together with at least the stent but not at some proximal part as claimed. However, since the Colombo teaches attachment of the elements together via the stent, it is the Examiner's position that it would have been obvious to attach the two elements together in some fashion particularly at the proximal end.

Regarding claim 69, Colombo fails to disclose a connector as claimed. However, since the stent performs the same function as a connector and since one could designate one module as the connector, the claimed invention would have been at least *prima facie* obvious to an ordinary artisan.

With regard to claims 72 and 73, Colombo teaches that it was contemplated to deliver a second prosthesis or stent into the side branch; see column 15, lines 52-64 and column 16, lines 44-67. Therefore, it is the Examiner's position that it would have

been obvious to use a second or branch stent deployment device to deliver the second stent in order to save time and thus the expense of performing the procedure.

Claims 14 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colombo, Uthmann, and Cameron as applied to claims 1, 3, 5-8, 10-13, 15-19, 42-48, 50-56, 58-70 and 72-73 above, and further in view of Davila et al (US 5,851,464). Colombo fails to disclose the use of pebax and graphite in the catheters. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to make the catheter of Davila out of pebax and graphite for the same reasons that Davila did the same and in order to promote sliding between the catheter and guidewire.

Response to Arguments

Applicant's arguments filed March 26, 2007 have been considered but they are not persuasive.

The specification and drawings objections have been withdrawn.

In response to the argument that Colombo does not disclose a side member held adjacent to the catheter at a location proximal the stent, the Examiner has modified the rejection to address this new claim requirement.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
Primary Examiner
Art Unit 3738